# SUBCHAPTER J—VACCINES

## PART 100—VACCINE INJURY COMPENSATION

Sec.
100.1 Applicability.
100.2 Average cost of a health insurance policy.
100.3 Vaccine injury table.

AUTHORITY: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); secs. 312 and 313 of Pub. L. 99–660, 100 Stat. 3779–3782 (42 U.S.C. 300aa–1 note); sec. 2114(c) and (e) of the PHS Act, 100 Stat. 3766 and 107 Stat. 645–646 (42 U.S.C. 300aa–14(c) and (e)); sec. 904(b) of Pub. L. 105–34, 111 Stat. 873; sec. 1503 of Pub. L. 105–277, 112 Stat. 2681–741; and sec. 523(a) of Pub. L. 106–170, 113 Stat. 1927–1928.

### § 100.1 Applicability.

This part applies to the National Vaccine Injury Compensation Program (VICP) under subtitle 2 of title XXI of the Public Health Service (PHS) Act.

[60 FR 7693, Feb. 8, 1995]

### § 100.2 Average cost of a health insurance policy.

For purposes of determining the amount of compensation under the VICP, section 2115(a)(3)(B) of the PHS Act, 42 U.S.C. 300aa.15(a)(3)(B), provides that certain individuals are entitled to receive an amount reflecting lost earnings, less certain deductions. One of the deductions is the average cost of a health insurance policy, as determined by the Secretary of Health and Human Services. The Secretary has determined that the average cost of a health insurance policy is $158.00 per month. This amount will be revised to reflect the changes in the medical care component of the Consumer Price Index (All Urban Consumers, U.S. City Average), published by the United States Bureau of Labor Statistics, plus 2 percent per year. The revised amounts will be effective upon their delivery by the Secretary to the United States Claims Court, and the amounts will be published in a notice in the FEDERAL REGISTER from time to time as determined by the Secretary.

[57 FR 28099, June 24, 1992, as amended at 60 FR 7693, Feb. 8, 1995]

### § 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub. L. 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

| Vaccine | Illness, disability, injury or condition covered | Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration |
|---|---|---|
| I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT). | A. Anaphylaxis or anaphylactic shock .... | 4 hours. |
| | B. Brachial Neuritis ..... | 2–28 days. |
| | C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | Not applicable. |
| II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP–Hib). | A. Anaphylaxis or anaphylactic shock .... | 4 hours. |
| | B. Encephalopathy (or encephalitis) ..... | 72 hours. |
| | C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | Not applicable. |

VACCINE INJURY TABLE—Continued

| Vaccine | Illness, disability, injury or condition covered | Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration |
|---|---|---|
| III. Measles, mumps, and rubella vaccine or any of its components (e.g., MMR, MR, M, R). | A. Anaphylaxis or anaphylactic shock .... | 4 hours. |
| | B. Encephalopathy (or encephalitis) ..... | 5–15 days (not less than 5 days and not more than 15 days). |
| | C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | Not applicable. |
| IV. Vaccines containing rubella virus (e.g., MMR, MR, R). | A. Chronic arthritis ..... | 7–42 days. |
| | B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | Not applicable. |
| V. Vaccines containing measles virus (e.g., MMR, MR, M). | A. Thrombocytopenic purpura ..... | 7–30 days. |
| | B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient. | 6 months. |
| | C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | Not applicable. |
| VI. Vaccines containing polio live virus (OPV). | A. Paralytic Polio | |
| | —in a non-immunodeficient recipient .. | 30 days. |
| | —in an immunodeficient recipient ..... | 6 months. |
| | —in a vaccine associated community case. | Not applicable. |
| | B. Vaccine-Strain Polio Viral Infection | |
| | —in a non-immunodeficient recipient .. | 30 days. |
| | —in an immunodeficient recipient ..... | 6 months. |
| | —in a vaccine associated community case. | Not applicable. |
| | C. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | Not applicable. |
| VII. Vaccines containing polio inactivated virus (e.g., IPV). | A. Anaphylaxis or anaphylactic shock .... | 4 hours |
| | B. Any acute complication or sequela (including death of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed.. | Not applicable. |
| VIII. Hepatitis B. vaccines ..... | A. Anaphylaxis or anaphylactic shock .... | 4 hours. |
| | B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed. | Not applicable. |
| IX. Hemophilus influenzae type b polysaccharide conjugate vaccines. | No Condition Specified ..... | Not applicable. |
| X. Varicella vaccine ..... | No Condition Specified ..... | Not applicable. |
| XI. Rotavirus vaccine ..... | No condition specified ..... | Not applicable. |
| XII. Vaccines containing live, oral, rhesus-based rotavirus. | Intussusception. ..... | 0–30 days. |
| XIII. Pneumococcal conjugate vaccines ... | No condition specified. ..... | Not applicable. |
| XIV. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage. | No Condition Specified ..... | Not applicable. |

(b) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table to paragraph (a) of this section:

(1) *Anaphylaxis and anaphylactic shock.* For purposes of paragraph (a) of this section, Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trchea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) *Encephalopathy.* For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) *For children less than 18 months of age* who present without an associated seizure event, an acute encephalopathy is indicated by a significantly decreased level of consciousness lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) *For adults and children 18 months of age or older,* an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

*(1)* A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(*2*) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(*3*) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A ''significantly decreased level of consciousness'' is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):

(*1*) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(*2*) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(*3*) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) *Chronic Encephalopathy* occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the

acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) [Reserved]

(4) *Seizure and convulsion.* For purposes of paragraphs (b) (2) of this section, the terms, ''seizure'' and ''convulsion'' include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(5) *Sequela.* The term ''sequela'' means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(6) *Chronic Arthritis.* (i) For purposes of paragraph (a) of this section, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/determatomyositis, fibromyalgia, necrotizing vascultitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction) metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

(iii) Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of paragraph (a) of this section.

(7) *Brachial neuritis.* (i) This term is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of

the injection; it is sometimes bilateral, affecting both upper extremities.

(ii) Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple monoeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(8) *Thrombocytopenic purpura.* This term is defined by a serum platelet count less than 50,000/$mm^3$. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(9) *Vaccine-strain measles viral infection.* This term is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(10) *Vaccine-strain polio viral infection.* This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(c) *Coverage provisions.* (1) Except as provided in paragraph (c)(2), (3) or (4) of this section, the revised Table of Injuries set forth in paragraph (a) of this section and the Qualifications and Aids to Interpretation set forth in paragraph (b) of this section apply to petitions for compensation under the Program filed with the United States Court of Federal Claims on or after March 24, 1997. Petitions for compensation filed before such date shall be governed by section 2114(a) and (b) of the Public Health Service Act as in effect on January 1, 1995, or by § 100.3 as in effect on March 10, 1995 (see 60 FR 7678, *et seq.*, February 8, 1995), as applicable.

(2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are included in the Table as of August 6, 1997.

(3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998. Vaccines containing live, oral, rhesus-based rotavirus (Item XII of the Table) are included in the Table as of October 22, 1998, provided that they were administered on or before August 26, 2002.

(4) Pneumococcal conjugate vaccines (Item XIII of the Table) are included in the Table as of December 18, 1999.

(5) Other new vaccines (Item XIV of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the FEDERAL REGISTER to announce the effective date of such a tax.

[60 FR 7694, Feb. 8, 1995, as amended at 62 FR 7688, Feb. 20, 1997; 62 FR 10626, Mar. 7, 1997; 63 FR 25778, May 11, 1998; 64 FR 40518, July 27, 1999; 67 FR 48559, July 25, 2002]

# PART 102—SMALLPOX COMPENSATION PROGRAM

Sec.



AUTHORITY: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 263 of the PHS Act, as amended, Public Law No. 108–20, 117 Stat. 638.

SOURCE: 68 FR 51497, Aug. 27, 2003, unless otherwise noted.

## §§ 102.1–102.20 [Reserved]

## §102.21 Smallpox (Vaccinia) Vaccine Injury Table.

(a) SMALLPOX (VACCINIA) VACCINE INJURY TABLE

| Injury (illness, disability, injury, or condition) | Time interval for first symptom or manifestation of onset of injury after: (1) administration of smallpox (vaccinia) vaccine in recipients (R); or (2) exposure to vaccinia in contacts (C) |
|---|---|
| 1. Significant Local Skin Reaction | R or C: 1–21 days. |
| 2. Stevens-Johnson Syndrome | R or C: 1–21 days. |
| 3. Inadvertent Inoculation | R or C: 1–21 days. |
| 4. Generalized Vaccinia | R or C: 1–21 days. |
| 5. Eczema Vaccinatum | R or C: 1–21 days. |
| 6. Progressive Vaccinia | R or C: 1–21 days. |
| 7. Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis. | R or C: 1–21 days. |
| 8. Fetal Vaccinia | Maternal R or C: any time in gestation until 7 days after birth. |
| 9. Secondary Infection | R or C: 0–30 days. |
| 10. Anaphylaxis or Anaphylactic Shock | R: 0–4 hours.<br>C: Not Covered. |
| 11. Vaccinial Myocarditis, Pericarditis, or Myopericarditis. | R or C: 1–21 days. |
| 12. Death resulting from an injury referred to above in which the injury arose within the time interval referred to above (except as specifically provided in specified paragraph (b) of this section). | R or C: No time interval specified. |

(b) *Table definitions and requirements* The Table Definitions that follow shall apply to, define and describe the scope of, and be read in conjunction with paragraph (a) of this section.

(1) *Significant local skin reaction*—(i) *Definition.* Significant local skin reaction is, for purposes of the Table, an unexpected and extreme response at the vaccination or inoculation site that results in a significant scar that is serious enough to require surgical intervention. The onset of this injury is the initial skin lesion at the vaccination or inoculation site that generally occurs with smallpox vaccinations or inoculations. Minor scarring or minor local reactions do not constitute a Table injury. Even a robust take, defined as an area of redness at the vaccination site that exceeds 7.5 cm in diameter with associated swelling, warmth and pain, in general is considered an expected response to the vaccination or inoculation. A robust take does not in itself constitute a Table injury, even when the redness and swelling involves the entire upper arm with associated enlargement and tenderness of the glands (lymph nodes) in the underarm (axilla).

(ii) *Table requirements.* A Table injury for a significant local skin reaction in a recipient or contact requires sufficient evidence in the medical records of the occurrence of a significant local skin reaction at the vaccination or inoculation site and a permanent, disfiguring scar that resulted from the significant local skin reaction. The scar must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records.

(2) *Stevens-Johnson Syndrome (SJS)*—(i) *Definition.* SJS (sometimes called erythema multiforme major) is an acute hypersensitivity reaction that affects

skin, mucous membranes, and sometimes internal organs (systemic toxicity). For purposes of the Table, both skin and mucous membrane rash or lesions must be present and the rash or lesions may not cover less than ten percent of body surface area. In SJS, mucosal involvement generally predominates. Mucosal lesions generally occur at more than one location and manifest as painful lesions in sites such as the mouth or eyes. Skin rash or lesions in SJS usually consist of red raised areas (erythematous macules), blisters, and ulcerations.

(ii) *Table requirements.* A Table injury for SJS in a recipient or contact requires sufficient evidence in the medical records of the occurrence of SJS. The SJS, or related complications, must be of sufficient severity to require inpatient hospitalization.

(3) *Inadvertent Inoculation (II)*—(i) *Definition.* II is the spread of vaccinia virus from an existing vaccination or inoculation site to a second location usually by scratching the vaccination or inoculation site and subsequently spreading the virus, which produces a new vaccinial lesion on the same person. Alternatively, II is the spread of vaccinia virus from an existing vaccination or inoculation site to another person usually by scratching an existing vaccination or inoculation site and subsequently spreading the virus, resulting in a contact case.

(ii) *Table requirements.* A Table injury for II in a recipient or contact requires sufficient evidence in the medical records of the occurrence of II and the occurrence of one of the following:

(A) Eye lesions, e.g., vaccinial keratitis or vaccinial blepharitis, that resulted from II and that led to a permanent sequela, e.g., decrease in visual acuity;

(B) Permanent and disfiguring scar(s) that resulted from II. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(C) Acute II or related complications of sufficient severity to require inpatient hospitalization.

(4) *Generalized Vaccinia (GV)*—(i) *Definition.* GV is a vaccinial infection that occurs from the spread of vaccinia from an existing vaccination or inoculation site to otherwise normal skin, resulting in multiple new areas of vaccinial rash or lesions. The vaccinia is believed to be spread through the blood. The rash or lesions are characterized by multiple blisters (vesicles or pustules) that generally evolve in a similar sequence or manner as the original vaccination or inoculation site.

(ii) *Table requirements.* A Table injury for GV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of GV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from GV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (*e.g.*, keloid) or functional (*e.g.*, contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute GV or related complications of sufficient severity to require inpatient hospitalization.

(5) *Eczema Vaccinatum (EV)*—(i) *Definition.* EV is the transmission or the spread of vaccinia virus from a vaccination or inoculation site to skin that has been affected by, or is currently affected with, eczema or atopic dermatitis. EV is characterized by lesions that include multiple blisters (vesicles or pustules), which generally evolve in a similar sequence or manner as the original vaccination or inoculation site. The lesions may come together to form larger lesions. Lesions may also spread to patches of skin that have never been involved with eczema or atopic dermatitis. A person with EV may be quite ill with signs and symptoms that involve the whole body (systemic illness), such as fever, malaise, or enlarged glands (lymph nodes).

(ii) *Table requirements.* A Table injury for EV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of EV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from EV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute EV or related complications of sufficient severity to require inpatient hospitalization.

(6) *Progressive Vaccinia (PV)*—(i) *Definition.* PV is the failure to initiate the healing process in an initial vaccination or inoculation site by 21 days after exposure to vaccinia with progressive ulceration or necrosis at the vaccination or inoculation site leading to a large destructive ulcer. PV is seen in people with an impaired immune system (immunocompromised) and is characterized by a complete or near complete lack of inflammation or absence of inflammatory cells in the dermis of the skin at the vaccination or inoculation site. The diagnosis of PV may be made before 21 days after exposure, especially in a known immunocompromised individual who develops a lesion at the vaccination or inoculation site. PV may spread through the blood to any location in the body. Any person who initiates a significant healing process of the vaccination or inoculation site by 21 days after receipt of the smallpox vaccine or exposure to vaccinia does not have PV.

(ii) *Table requirements.* A Table injury for PV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of PV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from PV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (e.g., keloid) or functional (e.g., contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute PV or related complications of sufficient severity to require inpatient hospitalization.

(7) *Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis (PVEM)*—(i) *Definition.* PVEM is, for the purposes of the Table, an autoimmune central nervous system injury. In rare cases, the vaccinia virus is isolated from the central nervous system. Manifestations usually occur abruptly and may include fever, vomiting, loss of appetite (anorexia), headache, general malaise, impaired consciousness, confusion, disorientation, delirium, drowsiness, seizures, language difficulties (aphasia), coma, muscular incoordination (ataxia), urinary incontinence, urinary retention, and clinical signs consistent with inflammation of the spinal cord (myelitis) such as paralysis or meningismus. Long term central nervous system impairments such as paralysis, seizure disorders, or developmental delays are known to occur as sequelae of the acute PVEM. No clinical criteria, radiographic findings, or laboratory tests are specific for the diagnosis of PVEM.

(ii) *Table requirements.* A Table injury for PVEM in a recipient or contact requires sufficient evidence in the medical records of the occurrence of acute PVEM. The acute PVEM or related complications must be of sufficient severity to require inpatient hospitalization.

(8) *Fetal Vaccinia (FV)*—(i) *Definition.* FV is an intrauterine vaccinial infection subsequent to vaccinia vaccination or inoculation of the mother that results from the placental transmission of the vaccinia virus during any time in the pregnancy. FV manifests as multiple skin lesions or organ involvement and may result in significant scarring or death. FV skin lesions are similar to those seen in GV or PV and the lesions may come together to form larger lesions. Congenital malformations, other than those described above, are not Table injuries.

(ii) *Table requirements.* A Table injury for FV requires sufficient evidence in the medical records of the occurrence of the FV. The occurrence of the FV or related complications must be of sufficient severity to require inpatient hospitalization or result in permanent and disfiguring scar(s). In addition, a Table injury for FV requires one of the following:

(A) A maternal history of vaccinial vaccination or inoculation, with the occurrence of vaccinial skin or mucous

membrane lesions within the incubation period for vaccinia during the pregnancy in a maternal recipient or contact; or

(B) Isolation of vaccinia from intrauterine or neonatal tissue.

(9) *Secondary Infection (SI)*—(i) *Definition.* SI is, for purposes of the Table, a non-vaccinial bacterial, fungal, or viral infection at the site of a vaccinial skin or mucous membrane lesion. SI occurs because the blister formation or ulceration that is part of the normal progression of a vaccinial skin or mucous membrane lesion disrupts the surface of the skin or mucous membrane, allowing potential germs to invade and infect the vaccinial skin or mucous membrane lesion leading to significant illness requiring hospitalization.

(ii) *Table requirements.* A Table injury for SI in a recipient or contact requires sufficient evidence in the medical records of the occurrence of SI. The acute SI or related complications must be of sufficient severity to require inpatient hospitalization.

(10) *Anaphylaxis or Anaphylactic shock*—(i) *Definition.* Anaphylaxis or anaphylactic shock is, for purposes of the Table, as an acute, severe, and potentially lethal systemic allergic reaction to a component of the smallpox vaccine.

(ii) *Table requirements.* A Table injury for anaphylaxis or anaphylactic shock in a recipient requires sufficient evidence in the medical records of the occurrence of an acute anaphylaxis or anaphylactic shock. The anaphylaxis or anaphylactic shock must be of sufficient severity to require inpatient hospitalization. Anaphylaxis or anaphylactic shock is not a Table injury for contacts.

(11) *Vaccinial Myocarditis, Pericarditis, or Myopericarditis (MP)*—(i) *Definition.* MP is, for purposes of the Table, vaccinial myocarditis, pericarditis, or myopericarditis. Myocarditis is defined as an inflammation of the heart muscle (myocardium). Pericarditis is defined as an inflammation of the covering of the heart (pericardium). Myopericarditis is defined as an inflammation of both the heart muscle and its covering. The inflammation associated with MP may range in severity from very mild (subclinical) to life threatening. In many mild cases, myocarditis is diagnosed solely by transient electrocardiographic (EKG) abnormalities (e.g., ST segment and T wave changes), increased cardiac enzymes, or mild echocardiographic abnormalities. Arrhythmias, abnormal heart sounds, heart failure, and death may occur in more severe cases. Pericarditis generally manifests with chest pain, abnormal heart sounds (pericardial friction rub), EKG abnormalities (*e.g.*, ST segment and T wave changes), and/or increased fluid accumulation around the heart.

(ii) *Table requirements.* A Table injury for MP in a recipient or contact requires sufficient evidence in the medical records of the occurrence of acute MP. The acute MP (or related complications) must be of sufficient severity to require inpatient hospitalization. A death resulting from MP requires sufficient microscopic (histopathologic) evidence of MP or its sequela in heart tissue.

(c) *Glossary for purposes of this section.*

(1) *Blister or vesicle* means a circumscribed, elevated skin or mucous membrane lesion containing an accumulation of fluid.

(2) *Contact* means a person who developed a vaccinial lesion or infection through inoculation (and not vaccination).

(3) *Exposure period* means the span of time during which vaccinia virus can be transmitted from a vaccine recipient shedding vaccinia or through a contact case shedding vaccinia.

(4) *Inoculation* means transmission of and infection with the vaccinia virus through a means other than smallpox vaccination. Spread (inoculation) of vaccinia virus may occur in two ways: either self-inoculation in which the vaccinia virus is spread from the vaccinial lesion at the vaccination site to one or more areas on the same person or person-to-person inoculation when the vaccinia virus is spread to another person, a contact.

(5) *Inoculation site* means the skin or mucous membrane surface where the vaccinia virus entered the body through means other than vaccination.

(6) *Lesion* means a pathologic change.

(7) *Pustule* means a circumscribed, elevated skin or mucous membrane lesion containing an accumulation of white blood cells.

(8) *Recipient* means a person to whom the smallpox vaccine was administered.

(9) *Ulceration* means a specific skin or mucous membrane lesion characterized by erosion of the skin or mucous membrane surface.

(10) *Vaccination* means the administration and receipt of the smallpox (vaccinia) vaccine, and not through contact.

(11) *Vaccination* site means the skin surface where the vaccinia virus entered the body through vaccination.

## PART 110 [RESERVED]